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a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position.

19. (Twice Amended) An artificial airway device comprising:
an air conduit extending between a proximal opening and a mask opening wherein, when the device is in an operative position, the proximal opening remains outside of a patient and the mask opening is open to a laryngeal opening of the patient;
a seating tip extending distally from the distal end of the airway tube which, when the device is in the operative position, is located on a pharyngeal side of a patient's cricoid; and
a surface angled relative to an axis of the air conduit and extending within the mask opening, wherein the angled surface is oriented so that, when the device is in the operative position, a plane in which the angled surface resides extends to the laryngeal opening of the patient.

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20. (Amended) The artificial airway device of claim 16, wherein the tube directing surface is formed by a portion of the at least one bar.

Remarks

I. Introduction

Claims 2-20 are currently pending. It is noted that the Office Action Summary erroneously states that claims 1-14 and 16-20 are pending. Claim 1 was previously canceled, without prejudice, in Applicants previously-filed Amendment filed on January 9, 2002. Claim 15 was not canceled and is therefore currently pending. Correction is respectfully requested.

Claims 2-20 stand rejected. It is noted that the Office Action Summary erroneously states that claims 1-14 and 16-20 are rejected. Correction is respectfully requested.

Claims 2, 19 and 20 have been amended without prejudice. No new matter has been added.

Claims 2-20 are hereby submitted for review and reconsideration.

II. Rejection of Claims 2-14, 16-18 and 20 Under 35 U.S.C. § 112

Claims 2-14, 16-18 and 20 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. With respect to claim 2, the Office Action contends that there is no antecedent basis for "the airway tube". With respect to claim 20, the Office Action contends that there is no antecedent basis for "the angled surface".

Applicant has amended claim 2 to delete the phrase "the airway tube" and to instead recite --the air conduit--. In addition, Applicant has amended claim 20 to delete the phrase "the angled surface" and to instead recite --the tube directing surface--.

In view of the foregoing, it is respectfully submitted that claims 2 and 20 fully comply with the requirements of 35 U.S.C. § 112, and withdrawal of this rejection with respect to claims 2 and 20 is therefore respectfully requested. Furthermore, it is respectfully submitted that claims 3-14 and 16-18, which ultimately depend from claim 2, fully comply with the requirements of 35 U.S.C. § 112 by virtue of the amendments made herein to claim 2, and withdrawal of this rejection with respect to claims 3-14 and 16-18 is therefore also respectfully requested.

III. Rejection of Claims 1-3, 6, 7 and 19 Under 35 U.S.C. § 102(e)

Claims 1-3, 6, 7 and 19 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,152,136 ("Pagan"). Applicants respectfully submit that Pagan does not anticipate claims 1-3, 6, 7 and 19 for the following reasons.

As an initial matter, it is noted that claim 1 was previously canceled, without prejudice, in Applicants previously-filed Amendment dated January 9, 2002. Thus, it is assumed that the Examiner's rejection of claim 1 was made in error, and that the Examiner intended to reject claims 2-3, 6, 7 and 19 in this paragraph. If Applicant is incorrect, clarification is respectfully requested.

Independent claim 2 relates to an artificial airway device comprising an air conduit extending between a proximal opening and a mask opening. When the device is in an operative position, the proximal opening remains outside of a patient and the mask opening is open to a laryngeal opening of the patient. The device also comprises a seating tip extending distally from the distal end of the airway tube. When the device is in the operative position, the seating tip is located on a pharyngeal side of a patient's cricoid. A first supporting arm extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative

position.

Furthermore, independent claim 19 of the present application relates to an artificial airway device comprising an air conduit extending between a proximal opening and a mask opening. When the device is in an operative position, the proximal opening remains outside of a patient and the mask opening is open to a laryngeal opening of the patient. The device also comprises a seating tip extending distally from the distal end of the airway tube. When the device is in the operative position, the seating tip is located on a pharyngeal side of a patient's cricoid. A surface is angled relative to the axis of the air conduit and extends within the mask opening. The angled surface is oriented such that, when the device is in the operative position, a plane in which the angled surface resides extends to the laryngeal opening of the patient.

Pagan purports to relate to a cuffed tube assembly. According to Pagan, an endotracheal tube has an inflatable cuff at its patient end enclosing a plate of generally triangular shape projecting forwardly of the patient end of the tube. Pagan states that when deflated, the cuff conforms to the external shape of the plate. The Office Action contends that "Pagan discloses an air conduit 1, a mask opening 5, supporting arms 17, compressible structure 2 and a seating tip 10." Office Action at p. 3.

Applicant respectfully maintains that Pagan does not teach or disclose the invention as recited in independent claim 2. For example, it is respectfully submitted that Pagan fails to disclose, or even suggest, a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, as recited in claim 2. According to one embodiment of the present invention, the support arms 145 are preferably curved to conform to the periform recesses of the esophagus. By contrast, the Examiner identifies item "17" of Pagan as "a supporting arm". As described in Pagan, "the plate 10 has two parallel low walls 17 projecting from its upper surface rearwardly of the forward part 16, which serves to locate the tube 1 centrally of the plate ...". As shown in Figure 2 of Pagan, these low parallel walls 17 merely orient the tube 1 relative to the expandable plate 10. The low parallel arms 17 do not extend axially from a seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, as recited in claim 2 of the present application. In addition, there are no other features of Pagan that extend axially from a seating tip in a shape substantially corresponding to that of a portion of the esophagus in

which the seating tip is located when the device is in the operative position.

Furthermore, Applicant respectfully maintains that Pagan does not teach or disclose the invention as recited in independent claim 19. For example, Pagan does not teach or disclose a surface angled relative to the axis of the air conduit and extending within the mask opening, wherein the angled surface is oriented so that, when the device is in the operative position, a plane in which the angled surface resides extends to the laryngeal opening of the patient, as recited in claim 19. According to one embodiment of the present application, an angled surface formed by the bars 143 is provided which assists in the insertion of a tube into the larynx of a patient via the airway tube. According to this embodiment, a tube threaded down the airway tube will contact the angled surface and be turned away from the axis of the airway tube and into the larynx. By contrast, Figure 2 of Pagan illustrates that the distal end of the air tube 1 is open and has no such angled surface.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Pagan does not disclose, or even suggest, all of the limitations recited in claims 2 and 19.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent

characteristics necessarily flows from the teachings of the applied art.” See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Pagan does not anticipate claims 2 and 19.

As for claims 3, 6 and 7, which ultimately depend from claim 2, it is respectfully submitted that Pagan does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 2.

IV. Rejection of Claims 2-9 and 19 Under 35 U.S.C. § 102(e)

Claims 2-9 and 19 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,119,695 (“Augustine et al.”). Applicants respectfully submit that Augustine et al. do not anticipate claims 2-9 and 19 for the following reasons.

Augustine et al. purport to relate to an airway device for sealing against the laryngeal opening that includes an air tube with proximal and distal ends and a sealing member attached to the distal end. The sealing member has a distal portion with a pair of opposing lateral flanges for engaging the cricoid cartilage to laterally align the sealing member with respect to the laryngeal inlet. The sealing member has a compressible anterior surface that contacts and seals against the laryngeal inlet. A tubular extension of the distal end of the air tube projects through and beyond the compressible anterior surface. The sealing member has a pronounced sigmoid shape having a lower section which, together with the tubular extension, creates a hook that provides an end point for accurate cephalad-caudad depth placement of the sealing member against the rim of the laryngeal inlet. The Office Action contends that “Augustine [et al.] disclose[] an air conduit 12, proximal opening 13, mask opening 35, compressible structure 30 or 38, supporting arms 24 and angles surface 28 extending within mask opening 35.” Office Action at p. 3.

Applicant respectfully maintains that Augustine et al. do not teach or disclose the invention as recited in independent claim 2. For example, it is respectfully submitted that Augustine et al. fail to disclose, or even suggest, a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the

esophagus in which the seating tip is located when the device is in the operative position, as recited in claim 2. As stated above, according to one embodiment of the present invention, the support arms 145 are preferably curved to conform to the periform recesses of the esophagus. By contrast, the Examiner identifies item "24" of Augustine et al. as "a supporting arm". As described in Augustine et al., "lateral flanges 24 ... rise upwardly along the sides 23 from the distal portion of the anterior support surfaces". Col. 5, lines 62-64 (emphasis added). In addition, Augustine et al. describe that "the lateral flanges [24] may have many shapes including, but not limited to, a wall, a tab, or a cylinder." Col. 9, lines 18-20. Thus, the lateral flanges 24 of Augustine et al. do not extend axially from the seating tip, but instead extend upwardly from the distal portion of an anterior support surfaces. Furthermore, the lateral flanges 24 of Augustine et al. do not extend in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, but instead are shown and described as having numerous possible shapes, none of which substantially corresponds to the shape of a portion of the esophagus.

Furthermore, Applicant respectfully maintains that Augustine et al. do not teach or disclose the invention as recited in independent claim 19. For example, Augustine et al. do not teach or disclose a surface angled relative to the axis of the air conduit and extending within the mask opening, wherein the angled surface is oriented so that, when the device is in the operative position, a plane in which the angled surface resides extends to the laryngeal opening of the patient, as recited in claim 19. As stated above, according to one embodiment of the present application, an angled surface formed by the bars 143 is provided which assists in the insertion of a tube into the larynx of a patient via the airway tube. According to this embodiment, a tube threaded down the airway tube will contact the angled surface and be turned away from the axis of the airway tube and into the larynx. By contrast, item "28" of Augustine et al. corresponds to a "tubular, 'snout-like' extension 28 that is a hollow cylinder". Col. 6, lines 10-12. Since the extension 28 is "hollow" and "tubular", it does not have a surface that is angled relative to the air conduit.

Thus, it is respectfully submitted that Augustine et al. do not disclose, or even suggest, all of the limitations recited in claims 2 and 19. As such, it is respectfully submitted that Augustine et al. do not anticipate claims 2 and 19.

As for claims 3-9 which ultimately depend from claim 2, it is respectfully submitted that Augustine et al. do not anticipate these dependent claims for at least the same

reasons given above in support of the patentability of claim 2.

V. Rejection of Claims 2-10 Under 35 U.S.C. § 102(e)

Claims 2-10 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 5,937,859 ("Augustine et al. II"). Applicants respectfully submit that Augustine et al. II do not anticipate claims 2-10 for the following reasons.

Augustine et al. II purport to relate to a laryngeal airway device includes an air tube with proximal and distal ends, and a padded sealing member attached to the distal end of the air tube. The sealing member is padded on its anterior surface and is adapted to seat in the throat, against the hyoid bone, and to stretch the laryngeal inlet. A hole extends through the anterior surface padding of the sealing member and communicates through an air passage with the distal end of the air tube. When the sealing member is seated in the throat, the hole is contained within the rim of the stretched laryngeal inlet, with which the padded surface forms a seal that surrounds the hole. Augustine et al. II purport that airway patency is thereby ensured. The Office Action contends that "Augustine [et al. II] disclose[] an air conduit 12, a seating tip 123, a mask opening 18, supporting arms between 123 and 127 in fig. 9b, fins on compressible member 16, 122." Office Action at p. 3.

Applicant respectfully maintains that Augustine et al. II do not teach or disclose the invention as recited in independent claim 2. For example, it is respectfully submitted that Augustine et al. II fail to disclose, or even suggest, a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, as recited in claim 2. As stated above, according to one embodiment of the present invention, the support arms 145 are preferably curved to conform to the periform recesses of the esophagus. By contrast, the Examiner seems to identify the curved portions of molded plastic support member 120, located between items labelled 123 and 127 in Figure 9(b), as "support arms". However, when the device of Figure 9(b) is assembled (Figure 9(b) shows an exploded view), the curved portions of molded plastic support member 120 are "sandwiched between" and entirely covered by the pad 16 and the posterior pad 122. Col. 10, lines 47-49. Thus, these curved portions serve no apparent purpose other than to provide surface area for the pad 16 and the posterior pad 122 to be glued thereto, col. 10, lines 34-40, and therefore do not extend in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, as

recited in claim 2.

Thus, it is respectfully submitted that Augustine et al. II do not disclose, or even suggest, all of the limitations recited in claim 2. As such, it is respectfully submitted that Augustine et al. II do not anticipate claim 2.

As for claims 3-10 which ultimately depend from claim 2, it is respectfully submitted that Augustine et al. II do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 2.

VI. Rejection of Claims 11-18 Under 35 U.S.C. § 103(a)

Claims 11-18 stand rejected under 35 U.S.C. 103(a) as unpatentable over Augustine et al. in view of U.S. Patent No. 4,995,388 ("Brain"). Applicant respectfully submits that the combination of Augustine et al. and Brain does not render obvious claims 11-18 for the following reasons.

Brain purports to relate to an artificial airway device. The Office Action contends that "Augustine [et al.] disclose[] the invention as claimed with the exception of the bars on the the mask opening", but that "Brain discloses the use of bars across a mask opening." Office Action at p. 4. The Office Action concludes that "it would have been obvious to have placed bars across the mask opening of Augustine, as taught by Brain, as this would prevent tissue [from] falling into the mask opening while still allowing for the passage therethrough of tubular element 28." Office Action at p. 4.

Claims 11-18 ultimately depend from claim 2, and therefore include all of the limitations of claim 2. As more fully described above, Applicant respectfully maintains that Augustine et al. do not teach or disclose the invention as recited in independent claim 2, for at least the reason that Augustine et al. fail to disclose, or even suggest, a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position, as recited in claim 2. Brain also does not disclose, nor is it relied upon by the Examiner to disclose, a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position.

To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to

make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Since the combination of Augustine et al. and Brain does not disclose, or even suggest, all of the limitations of claim 2, as more fully set forth above, it is respectfully submitted that the combination of Augustine et al. and Brain does not disclose, or even suggest, all of the limitations of claims 11-18 which depend from claim 2. Thus, it is respectfully submitted that the combination of Augustine et al. and Brain does not render obvious claims 11-18.

Moreover, it is respectfully submitted that the cases of In re Fine, *supra*, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Office Action's generalized assertions that it would have been obvious to modify or combine the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the reference relied upon. In particular, the Court in the case of In re Fine stated that:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done.

...

Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .

Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to modify or combine references to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the reference to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" -- which is not the case here -- there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

In summary, since claims 11-18 depend from independent claim 2, and since Brain simply does not cure the critical deficiencies of Augustine et al., as more fully described above, it is respectfully submitted that claims 11-18 are allowable for at least the same reasons that claim 2 is allowable. In re Fine, supra. Withdrawal of this rejection is therefore respectfully requested.

Fees

Any additional fees or charges required at this time in connection with this application may be charged to Patent and Trademarks Office Deposit Account No. 11-0600.

Conclusion

In view of the aforementioned amendment and remarks, it is respectfully submitted that all claims currently pending in the above identified application are now in condition for allowance, the earliest possible notice of which is earnestly solicited. If in the Examiner's opinion the prosecution of the present application would be advanced by a telephone interview, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Version with Markings to Show Changes Made

2. (Twice Amended) An artificial airway device comprising:

an air conduit extending between a proximal opening and a mask opening wherein, when the device is in an operative position, the proximal opening remains outside of a patient and the mask opening is open to a laryngeal opening of the patient;

a seating tip extending distally from the distal end of the [airway tube] air conduit which, when the device is in the operative position, is located on a pharyngeal side of a patient's cricoid; and

a first supporting arm that extends axially from the seating tip in a shape substantially corresponding to that of a portion of the esophagus in which the seating tip is located when the device is in the operative position.

19. (Twice Amended) An artificial airway device comprising:

an air conduit extending between a proximal opening and a mask opening wherein, when the device is in an operative position, the proximal opening remains outside of a patient and the mask opening is open to a laryngeal opening of the patient;

a seating tip extending distally from the distal end of the airway tube which, when the device is in the operative position, is located on a pharyngeal side of a patient's cricoid; and

[an angled] a surface angled relative to an axis of the air conduit and extending within the mask opening, wherein the angled surface is oriented so that, when the device is in the operative position, a plane in which the angled surface resides extends to the laryngeal opening of the patient.

20. (Amended) The artificial airway device of claim 16, wherein the [angled] tube directing surface is formed by a portion of the at least one bar.